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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,933	09/20/2001	Luba Cohen	2786-0191P	9933

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/955,933

Applicant(s)

COHEN, LUBA

Examiner

Deborah K. Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7-11,13-17 and 19-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5, 7-11, 13-17 and 19-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>12/13/06</u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-2, 5, 7-11, 13-17 and 19-32 are pending.

Interview

Applicant's request filed December 7, 2006 for interview was granted and such interview was conducted on December 13, 2006, a copy of the interview summary record is attached hereto.

Response to Amendment

The amendment, power of attorney, and extension of time filed December 14, 2006, were received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claims 2, 5, 24-29 and 31-32 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Since each of claims 1, 9 and 23 as well as other base claims recite Markush closed language for which to define the conditions and risk factors, these dependent claims do not further limit the components of the Markush groups of the claims from which they depend because the term "comprises" opens up these claims to include other conditions and risk factors in the dependent claims. Thus, the term "comprises" as used in these objected claims is suggested to be changed to --is--.

Claims 13-14 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 11. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 19-20 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 17. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 5, 7-8, 11, 13-14, 17, 19-20, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims are rendered vague and indefinite because claim 1 does not clearly recite each component of the Markush Group. The component recited as "high concentration" is vague and indefinite as to what the component is per se. The metes and bounds of the claims can not be, therefore, determined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 5, 7-11, 13-17 and 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over newly cited Sha et al (6280776) in view of previously cited Furhman et al.

Claims are drawn to methods for lowering risk factors and conditions in a patient selected from amongst high blood pressure, high blood glucose, high blood triglycerides, high cholesterol, hypertension, etc. Further, the methods are carried out by administering a licorice extract which is water-insoluble and free from glycyrrhizinic acid.

Sha et al teach methods for lowering risk factors and conditions in a patient selected from amongst high blood pressure, high blood glucose, high blood triglycerides, high cholesterol, hypertension, etc, see abstract. Further, the methods are carried out by administering a licorice extract, note column 4, line 16.

Furhman et al teach administering a licorice extract which is water-insoluble and free from glycyrrhizinic acid. Note page 268, column 1, "Materials" lines 1-2. An ethanol is used to extract the licorice, note page 270, column 2, only paragraph, lines 9-10. The licorice extract is disclosed to have a protective effect against LDL oxidation.

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The claimed licorice extract and that disclosed by Furhman et al are identical and hence has been admitted by Applicants.

The claims differ from Sha et al in that the licorice extract is not disclosed to be water insoluble and made from ethanol and hence the licorice extract is different, however, the conditions and risk factors treated as claimed are disclosed by Sha et al.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to replace the licorice extract disclosed by Sha et al with that disclosed by Furhman et al because one of skill would have been motivated to minimize LDL oxidation in Sha et al to achieve enhanced expected results of lowering the risk factors and conditions of these problematic diseases associated with LDL oxidation. Each of the newly claimed features and limitations are disclosed by the cited prior art combination and in the absence of persuasive evidence to the contrary the claims are prima facie obvious.

Response to Arguments

Applicant's arguments filed December 14, 2006, have been fully considered but they are not persuasive. The argument that Furhman et al is silent regarding the newly claimed risk factors and conditions is noted, however, in light of the newly applied art reference, Sha et al, the argument is not persuasive. Note both references teach licorice extract provides successful results and hence to switch one for the other would have provided an expected successful result.

Also Applicant admits that the licorice extract of Furhman et al is identical to their licorice extract and the results of lowering certain risk factors and treating conditions

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would have been intrinsic because it is the same extract which is being administered to a patient. No other result would be expected to be obtained other than a successful one.

As noted by Sha et al all of the conditions and risk factors are already known to be treated with licorice extract. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Therefore, in view of the newly applied art rejection the arguments are not persuasive.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah K. Ware
March 3, 2007



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128/657